UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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Memorandum

Subject: Lower Risk Pesticide Chemical Focus Group's Assessment for Nitrogen Tolerance Reassessment

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The following is the Lower Risk Pesticide Chemical Focus Group's science assessment for nitrogen (PC Codes 128934, 900206). The purpose of this review is a reassessment of the exemption from the requirement of a tolerance under 40CFR 180.1050. This assessment summarizes available information on nitrogen. In performing this assessment, EPA has relied on a peer-reviewed evaluation performed by the Food and Drug Administration (FDA).

Nitrogen (N_2) is a colorless, odorless gas which comprises approximately 78 percent of the earth's atmosphere. It is relatively inert, non-combustible, and slightly soluble in water. Nitrogen is an essential component of all plant and animal life, and is present in all living tissues of the human body. During human respiration, about 350 grams of nitrogen move through the lungs per hour. As a primary constituent of amino acids, nitrogen is also present at high levels in the normal human diet.

Nitrogen is used commercially to generate an inert atmosphere usually for product packaging. In the food industry, it is used to preserve packaged foods, such as ground coffee, by displacing oxygen. As a pesticide active ingredient, nitrogen may be used as a fumigant to control insects in structures and on stored food commodities. Currently there is only one registered end-use product containing nitrogen as the active ingredient. As a pesticide inert it is used as an aerosol propellant.

The Food and Drug Administration (FDA) has classified nitrogen as Generally Recognized As Safe (21CFR 184.1540) as a direct food additive. The 1979 FDA evaluation of nitrogen entitled "Evaluation of the Health Aspects of Nitrogen, Helium, Propane, *n*-Butane, *iso*-Butane, and Nitrous Oxide as Gases used in Food" considers the essential role of nitrogen in the human body and human exposure levels through normal respiration and diet. As a result, the FDA evaluation concludes that "[t]here is no evidence in the available information on nitrogen gas that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when it is used at levels that are now current or that might reasonably be expected in the future."

Based on the available information on nitrogen, its expected use pattern, its safe history of use as a food additive, and its essential role in the human body, there is a reasonable certainty of no harm from exposure to nitrogen through its use in pesticides. Furthermore, there is no concern for potential sensitivity to infants and children. It is known that direct contact with liquid nitrogen may cause dermal corrosion, and that exposure to atmospheres containing very high levels of nitrogen could result in asphyxiation through displacement of oxygen. However, as with all chemicals, nitrogen must be used safely according to good manufacturing or good agricultural practices. The Agency believes that exposure to levels of concern of nitrogen are unlikely as a result of its use in pesticide products, and would be most appropriately addressed through the use of protective equipment, adequate ventilation, and labeling, not through the establishment of tolerance exemptions.

References:

U.S. Food and Drug Administration (FDA), 1979. Evaluation of the Health Aspects of Nitrogen, Helium, Propane, *n*-Butane, *iso*-Butane, and Nitrous Oxide as Gases used in Foods. Prepared by Life Sciences Research Office, Federation of American Societies for Experimental Biology.